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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,013	04/28/2005	Koushi Nakano	Saeg153.002APC	1676

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

NOTIFICATION DATE	DELIVERY MODE
08/01/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,013	NAKANO ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,24 and 25* is/are pending in the application.

4a) Of the above claim(s) *13-20,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-20, 24, and 25 are pending. Claims 1, 5, 7, and 9 are currently amended and claims 21-23 are canceled by Applicant's response, filed 5/18/2007.

Election/Restrictions

2. Claims 12-20, 24, and 25 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/18/2006.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

2. The rejection of claims 1-12, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a non-human animal model exhibiting prostate tissue damage characteristic of chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in chronic nonbacterial prostatitis wherein in the animal model is prepared by injection of hydrochloric acid (HCl), wherein the HCl

concentration ranges from 0.1 N to 0.4 N, a method of using said nonbacterial prostatitis non-human animal model comprising administering a test substance and determining if it alleviates prostate tissue damage or lower urinary tract disorder symptoms, and a method of making said non-human prostatitis animal model comprising injecting HCl beneath the prostatic capsule wherein the HCl is between 0.1 N and 0.4 N, does not reasonably provide enablement for a nonbacterial prostatitis animal model produced using any concentration of HCl, is withdrawn.

Applicant amended the claims to further narrow the range of HCl treatment to 0.1N to 0.4N which was deemed enabled because the specification discloses that this specific range results in the claim prostatitis model. Therefore, the rejection is withdrawn.

New Matter

3. The rejection of claim 5, under 35 U.S.C. 112, first paragraph, as containing new matter in its recitation of "4 days to 1 week", is withdrawn.

Applicant removed this recitation and replaced it with "4 days to 8 days". This removal of the prior recitation, "4 days to 1 week", removed the new matter and therefore, the rejection is withdrawn.

Applicant points to page 23, lines 10-13 and page 22, lines 19-22 of the specification as support for the new recitation. Page 23, lines 10-13 disclose that the animal models undergo at least 4 days and more preferable at least 8 days of rearing after HCl injection. Page 22, lines 19-22 disclose an animal model that has undergone

8 days of rearing following HCl is preferable because the animal model mimics the pathology of human chronic nonbacterial prostatitis. These cited disclosures by the specification support the new recitation of "4 days to 8 days" and therefore they do not introduce new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (of record; 2000), Keetch et al (of record, 1994), Fulmer et al (of record;

2000), Robinette (of record, 1988), and Royston D (Acta anaesthesiologica Scandinavica 30(7):abstract, 1986), in view of Goto (of record; 1988).

Applicant traverses this rejection on the grounds that none of the arts in the rejection teach the injection of the HCl beneath the prostatic capsule and that the animal model exhibits tissue damage in prostate tissue and the surrounding tissue that is characteristically observed in human chronic nonbacterial prostatitis as well as pathology of a lower urinary tract disorder. Furthermore, none of the arts discloses the same model because they would not result in a nonbacterial prostatitis models with lower urinary tract disorders because the agents administered are different and the tissues in which they are injected are different.

Applicant's arguments are not found persuasive. First, Applicant's arguments that the art does not teach or make obvious the specific pathology of a lower urinary tract disorder is not found persuasive. As previously stated on page 10 of the Office Action, mailed 7/14/2006, "Lang et al also teach that some of the rats developed severe prostatitis, prostatic urethral occlusion, and urinary retention (p. 203, col 1, lines 8-11), which would be considered a lower urinary tract disorder as well as bladder disorder. Inherently this would also result in an increase in bladder weight to body weight (claim 2) and potentially reduced effective bladder capacity (claims 3) as claimed. Overall, Lang et al teaches that a more severe case of prostatitis will lead to lower urinary tract disorders. This is similar to what is seen in human prostatitis as well." Therefore contrary to Applicant's assertion, the Lang et al disclosure of urethral retention and

urethral occlusion embraces a lower urinary tract disorder and that it is similar or mimics human prostatitis.

Second, Applicant's arguments that the art does not teach or make obvious administering the HCl beneath the prostate capsule is not found persuasive as well. As previously stated on page 11 in the Office Action, mailed 7/14/2006, "Lang et al also fails to teach injection into the dorsolateral lobe. However, Lang et al. and the art of record demonstrate that administering to a specific area of the prostate does not limit its impact to other areas of the prostate [*sic*; adjacent tissues]. For example, delivery to the vas deference of HCl still resulted in prostatic damage as evidenced by Goto et al (of record)." The art also teaches that HCl is a non-specific irritant that functions in a non-tissue specific manner to cause tissue damage and pathology, as taught by Royston et al demonstrating that similar tissue damage is caused by administration of HCl in other tissue types (see page 9 of the Office Action, mailed 7/14/2006)

Therefore, because HCl functions in a non-specific manner to cause tissue damage and pathology, as taught by Royston et al, and administration of HCl or other non-specific irritants do not limit its impact to the site of administration and affect near by tissues, as taught by Lang et al, Goto et al, and the other art of record, it would be obvious to an artisan that administration of HCl to the prostate, beneath the prostate capsule, or in the vas deference would cause symptoms of prostatitis, tissue damage, and pathology to the prostate and to tissue in the vicinity of the site of administration with an art supported reasonable expectation of success.

Third, it is noted that Applicant uses the argument that the animal model exhibits tissue damage in prostate tissue and the surrounding tissue to differentiate the instant invention from the art. However, while it may be the intent of Applicant to encompass this limitation by the claims, it is not a requirement by the claims. Furthermore, as taught above and in the previous Office Actions, the art clearly teaches this limitation.

Fourth, Applicant asserts that the instantly claimed animal model is different from that disclosed in the art and would not be made obvious by the art because the art teaches different agents and different tissues. This argument is not considered persuasive because collectively the art teaches that HCl has been used in the art to cause non-specific tissue damage, pathology, and inflammation and it has more specifically been used to induce nonbacterial prostatitis as seen in Gotto et al. The art does render the instant invention obvious. The context of art that teaches HCl treatment in other tissues was presented to demonstrate the non-specific nature of HCl to cause tissue damage, such as Royston et al, and the art demonstrating different irritants and agents to produce nonbacterial prostatitis where used to demonstrate that many agents have been use to make prostatitis model. Therefore, although these art teach different tissues and agents they were relied upon to demonstrate that the state of the art, the nature of the agents used, and that they affect tissues is a similar manner resulting in the same phenotypes embraced by the claims, and therefore, it is not relevant in isolation that these art did not teach the specific embodiments because they are supportive to the over all art that does teach the instant invention as claimed. Therefore, Applicant's argument is not found persuasive.

Therefore, because the amendments to the claims and Applicant's arguments are not found persuasive, the instant rejection of record is maintained.

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

AU 1632

PETER PARAS, JR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600